AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,067	12/13/2004	Carsten Pilger	MG-2519	2721

23416 7590 01/03/2006

CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/518,067	PILGER ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/518,067 filed on 12/13/2004. Claims 1-12 are pending and are accordingly presented for examination on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claim 7 is objected to because of the following informalities: AIDS dementia is recited twice. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter. The limitation of instant claim 1 is drawn to xenon gas with an intended use as an adjuvant. The Examiner interprets this to read upon xenon gas, which is a natural product.

Claim Rejections - 35 U.S.C. §§ 101 and 112, Second Paragraph

The following are quotations of 35 U.S.C. §§ 101 and 112, second paragraph, respectively, which form the basis of the claim rejections as set forth under this particular section of the Official Action:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims, as defined in 35 U.S.C. § 101. See, *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967). In addition, claims 8 and 9 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, a claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). As a result, the Applicants are respectfully required to redraft the aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishman (US 5,228,434).

Instant claim 1 is drawn to an adjuvant comprising xenon or a xenon-containing gas.

Fishman disclose a mixture consisting of from 60 to 78.5 mole percent stable xenon, from 19.5 to 38 mole percent oxygen and from 2.5 to 20.5 mole percent helium (Claim 1). Methods of making and methods of using the gas mixture are disclosed (Column 3, lines 14-42 and column 5, lines 8-36) and use of the gas mixture in combination with intravenously introduced methyl-atrophine bromide, thiopentone and fentanyl (Column 5, lines 10-13). In addition the Examiner interprets oxygen as a therapeutic active ingredient (a migraine remedy) that will enter the bloodstream and thus read on instant claims 1-3, and 6-11. Please note that for purposes of examination, the Examiner is interpreting instant claim 6 to read upon any combination of xenon and an administered therapeutic agent; instant claim 8 as a method of making a product and instant claim 9 to read upon a product with an intended use. The mixture is administered to the patient by a re-breathing system and therefore reads on instant claim 4 (Column 5, lines 19-26 and claim 4). The gas mixture is provided to the patient

in sufficient amount to anesthetize the patient and thus reads on instant claims 5 and 12.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (instant claim 9), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Claim Rejections - 35 USC § 102

Claims 1-12 rejected under 35 U.S.C. 102(b) as being anticipated by Petzelt et al. (WO 00/53192).

Petzelt et al. disclose preparations and methods of use of xenon or xenon gas mixtures for treating neurointoxications (a chronic cerebral disorder such as Parkinson's disease) in a therapeutically useful concentration (Page 5, paragraph 1; page 11, paragraph 4 and claims 1, 7 and 16, for example). The preparation can have a ratio of xenon to oxygen of 80 to 20 percent by volume (Page 8, second paragraph and claim 15). Administration is by simple inhalation (Page 12, line 1). Methods of mixing the

gases are provided (Page 8, paragraphs 3 and 4). Methods of administration are also provided (Page 9, paragraphs 1 and 2).

Claim Rejections - 35 USC § 102

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lecourt et al. (US 2002/0033174).

Lecourt et al. disclose an inhalable medicaments and their use in therapeutically effective amounts wherein the gas can be xenon and the active product is chosen from among paracetamol, acetylsalicylic acid, arylcarboxylic acid, corticosteroids, mineralosteroids, non-steroidal anti-inflammatory drugs and their derivatives, codeine and its derivatives, morphine and morphine mimetics (Abstract and claims 1, 4, 12 and 13). Lecourt et al. disclose xenon and steroidal anti-inflammatory active principles as combinations with potential synergistic effects (Page 3, [0059]).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (instant claim 9), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Claim Rejections - 35 USC § 102

Claims 1, 2, 6-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Georgieff (US 6,197,323).

Georgieff discloses a preparation, which contains a lipophilic gas (xenon) in a liquid preparation in combination with additional pharmacologically active agents (Abstract; column 8, lines 36-60 and claims 1, 6 and 9-12). The liquid preparation is intended for inducing sedation, analgesia, as a muscle relaxant or as an anti-inflammatory (Column 8, line 61 to column 9, line 17 and claims 2-5). Methods of making the preparation are disclosed (Column 10, line 21 to column 11, line 2). Methods of administration by injection and infusion are disclosed (Column 7, lines 38-58; column 11, lines 4-32 and column 12, lines 43-61).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (instant claim 9), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Claim Rejections - 35 USC § 102

Claims 1, 2, 6-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Franks et al. (WO 00/76545).

Franks et al. disclose a pharmaceutical composition comprising an NMDA antagonist (xenon) and an alpha 2 adrenergic agonist (Abstract and claims 1-3). The pharmaceutical composition can be used to diminish the harmful effects of stroke, provide neuroprotection after trauma, relieve pain, provide sedation, reduce anxiety and to prevent convulsions (Page 17, lines 15-22, page 18, lines 13-32 and claims 7-9). The pharmaceutical composition may be delivered intravenously, neuraxially or transdermally (Page 16, lines 1-4). The components of the formulation may be administered consecutively, sequentially or simultaneously (Page 10, lines 27-28). The concentrations employed in the formulation may be the minimum concentrations required to achieve the desired clinical effect (Page 16, lines 17-18).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (instant claim 9), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant

case, the intended use does not create a structural difference, thus the intended use is not limiting.

Double Patenting

1) Claims 1, 3 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-27 and 32 of copending Application No. 10/380,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. Instant claim 1 is embraced by copending claim 22. Instant claim 3 is embraced by copending claims 24 and 25. Instant claim 12 is embraced by copending claim 27.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2) Claims 1-6, 8 and 10-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 7 and 9 of copending Application No. 10/517,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. Instant claim 1 and copending claim 1 recite the same composition. The Examiner interprets NO to be a hemogenous medicament because it is transported by the blood stream and thus copending claim 3

makes obvious instant claim 2. Copending claims 1 and 2 make obvious gaseous xenon present in a therapeutically effective amount of instant claims 3, 5, 10 and 12. Oral administration of copending claim 4 makes obviosu upon inhalation of instant claims 4 and 11. Copending claim 4 also makes obvious simultaneous, separate or sequential use of instant claim 6. Copending claim 7 recites production of a medicament to treatment of brain disorders, which makes obvious instant claim 8.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3) Claims 1-6, and 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/517,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. Instant claim 1 and copending claim 1 recite the same composition. The Examiner interprets NO to be a hemogenous medicament because it is transported by the blood stream and thus copending claim 4 makes obvious instant claim 2. Copending claims 1 and 2 make obvious gaseous xenon present in a therapeutically effective amount of instant claims 3, 5, 10 and 12. The gaseous preparation of copending claim 4 makes obvious inhalation of instant claims 4 and 11. Copending claim 4 also makes obvious simultaneous, separate or sequential

use of instant claim 6. Copending claim 6 recites production of a medicament to treatment of brain disorders, which makes obvious instant claim 8. Copending claim 7 is drawn to the use of a xenon gas mixture for cerebral protection which makes obvious instant claim 9.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA

JOHN PAK
PRIMARY EXAMINER
GROUP 1600